Antibiotics for Spinal Cord Stimulation Trials

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Myth #1: Patients undergoing spinal cord or dorsal root ganglion stimulation trials must be kept on prophylactic antibiotics throughout the entire course of either a percutaneous or staged trial while electrodes remain externalized.

Myth #2: Only patients undergoing a staged trial should be placed on prophylactic antibiotics during the trial period.

Fact: In low risk patients, it may not be necessary to continue antibiotics throughout the percutaneous or staged trial period; however, in high-risk patients, or in trials lasting more than five days, antibiotics should be considered on a case-by-case basis.

Spinal cord stimulation (SCS) and dorsal root ganglion (DRG) stimulation are evidence-based procedures used to treat a variety of chronic pain conditions. Although the electrodes that provide stimulation can be directly implanted, patients typically undergo a trial period of stimulation in order to provide confidence that implantation will result in pain and functional improvement [1]. There are two strategies for placement of electrodes during a trial, detailed below. In both cases electrodes remain externalized for the duration of the trial. This forms a potential conduit between the skin and the deeper tissue planes, which may inadvertently facilitate an infection. The literature poorly discriminates between infections following a trial period or infections following permanent implantation [2]. This has contributed to heterogeneous practice patterns surrounding antibiotic use during the trial period.

While there are general recommendations addressing antibiotic use in SCS, existing guidelines [2,3] do not adequately address its use in the trial period when leads are externalized. These guidelines recommend preoperative antibiotic prophylaxis be administered 30-60 minutes before insertion/incision with doses determined on the basis of patient weight. They advise against continuation of antibiotics beyond one dose for both neuromodulation trials and implants. An international survey of more than 500 physicians investigating infection control practices for SCS reported that about 50% of respondents continued antibiotics into the postoperative period [4]. Of the respondents that continued antibiotics post-operatively during the trial period, 90.2% (244) did so for more than 24 hours. In this study, two factors cited for consideration when determining whether or not to continue antibiotics during the trial period were: 1) the type of trial performed, and 2) the anticipated duration of the trial.

Trial Type

Multiple strategies exist for the trialing of neuromodulation devices, but the two most common consist of either a percutaneous trial followed by a separate full implant, or a staged trial and direct implant. In the first method, temporary electrodes are placed percutaneously and attached to an external pulse generator/battery for the duration of the trial. The temporary electrodes are removed at the end of the percutaneous trial. Subsequent implantation with permanent leads may be undertaken several weeks later. With a staged trial, the “trial” stimulating electrodes become the permanent electrodes and are anchored to the fascia before being connected to temporary extension leads that are tunneled to the region of the pulse generator/battery location and externalized for the trial period. This necessitates a more extensive surgical implantation procedure during the trial lead placement than if percutaneous leads are removed at the conclusion of the trial period. In the
survey referenced above, 96.8% of the respondents from the United States reported using the percutaneous trial and implant pathway [4].

Previous concerns have been raised regarding the possibility of increased infection rates associated with the staged trial pathway, though the current literature often does not discriminate between the technique of SCS during the test period and the implantation when reporting infection rates [2]. May et al. reported on the first 59 SCS patients (1993-1997) undergoing staged trials, and 18.6% [95% confidence interval (CI): 9.7-90.9%; 11 patients] had an infection necessitating antibiotic therapy and a delay before permanent system implant [5]. Improvements in technique and wound dressing in a subsequent series reduced the trial infection rate to 7.5% (95% CI: 1.6-20.4%; 3 of 40 patients), with all of the infections being superficial. Rudiger et al. also evaluated staged trials and reported an infection rate of 1.2% (95% CI: 0.6-5.5%; 1 of 84 patients) [6]. A 2007 study of patients who underwent either a percutaneous or staged trial demonstrated similar results with only one infection in 65 SCS trials (1.5%, 95% CI: 0.8-3%), though the study did not specify if the infection developed with a percutaneous or staged trial [7].

Additionally, in a retrospective review of 286 patients comparing outcomes and adverse events between percutaneous and staged trials, Simopoulos et al. observed a lower infection rate in the percutaneous trial group (1.35%; 95% CI: 0.4%-2.3%; 2 of 148 patients) compared to the staged trial group (6.5%; 95% CI: 4.4%-8.6%; 9 of 138 patients), which was statistically significant (p=0.02) [8]. Conversely, a large, multicenter, retrospective observational analysis of 2,737 SCS implants or revisions by Hoelzer et al. found that permanent implants after a staged trial had an infection rate of 0.9% (95% CI: 0.4-1.9%; 7 of 753 patients), while permanent implant after a percutaneous trial had an infection rate of 2.1% (95% CI: 1.3-2.9%; 27 of 1,308 patients) [9].

**Trial Duration**

Many key SCS efficacy studies have relied on an extended trial period as part of their selection criteria [7,10,11]. In a review of 84 patients with SCS implantations, Rudiger et al. reported an average screening trial period of nine days, with a range between four and 29 days [6]. In the review above by Hoelzer et al., the average trial length was 4.8 days (no range was provided) [9]. The same review also found that patients who underwent permanent implantation of an SCS system after a previous trial lasting more than five days had a significantly higher risk of infection than those whose trial was five days or fewer (3.7% and 1.6%, p = 0.05). Importantly, these infections affected the permanent implant and not the trial itself. A common assumption that a longer trial provides greater opportunity for infection to develop anywhere between the skin and the spinal canal may be reflected by these data.

In another retrospective review of 707 SCS cases, Mekhail et al. suggested that an adequate trial lasting from five to 14 days is required for appropriate patient selection, as SCS implantation in poorly selected patients may be potentially harmful and costly [12]. This review reported an SCS-related infection rate of 4.5% (95% CI 3.1-6.3; n=32), but did not specify if these infections were trial or implant related.

**Comorbidities**

It has been established that certain comorbidities – including tobacco use, uncontrolled diabetes, malignancy, human immunodeficiency virus (HIV), untreated remote infections, *Staphylococcus aureus* carriers, and preoperative steroid use – may result in a greater risk of infections in other surgical arenas [13-17]. But the question of whether or not this increased risk exists throughout the SCS trial period is unclear. In the retrospective review by Hoelzer et al., no statistically significant differences in SSI rate with obesity, diabetes, or tobacco use were identified, but it should be noted that the data are referring to SCS implants, and not the trials [9]. Additionally, in this same study, 2024 out of 2586 cases (78.4%) received post-operative antibiotics with an infection rate of 1.78% (n=36), while patients not receiving post-operative antibiotics had an infection rate of 4.09% (n=23, p=0.001). Individual data on those patients with comorbidities receiving post-operative antibiotics versus those with comorbidities who did not receive post-operative antibiotics are not available. The average duration of prescribed post-operative antibiotics was 7.6 days. Notably, in the study by Mekhail et al., patients with diabetes and failed back surgical syndrome (FBSS) showed increased rates of infection (9% and 6.3 %, respectively) beyond the average incidence of 4.5% with implantation, but neither was found to be statistically significant [12]. No infections were documented in any of the 707 SCS trials, but the authors did not disclose the antibiotic regimen used during the trial period.
Spinal Epidural Abscess

Perhaps the most concerning complication related to SCS or DRG lead placement is the potential development of a spinal epidural abscess (SEA). The retrospective study by Mekhail et al. reported 18 cases of SCS-related SEAs, but none apparently occurred during the trial [12]. There are only two peer-reviewed case reports of SEA developing specifically during an SCS trial. The first case in 2008 involved a 46-year-old male, smoker with FBSS, who underwent placement of percutaneous leads without receiving any pre- or post-procedure antibiotics. The SEA became apparent on post-op day five [18]. In the second case, a 54-year-old healthy female with lumbar radiculopathy underwent a percutaneous trial with 2 grams of intravenous cephazolin for prophylaxis and was discharged with no additional antibiotics [19]. On trial day four, her leads were removed and oral antibiotics were initiated because of fever. SEA was discovered on post-op day five.

Conclusions and Recommendations

1) SCS and DRG stimulation trials have a reported infection rate of 1-18% [2,4-10]. Significant reductions in infection rates have been achieved during the past decade. In the largest contemporary evaluation of SCS-related infections, Hoelzer et al. calculated an infection rate of 2.45%, which is comparable to the general incidence of surgical site infections across multiple surgical specialties [9,20].

2) It remains undetermined whether percutaneous or staged stimulator trials have a higher infection rate, as studies have shown conflicting results.

3) All appropriate measures should be taken to limit infection risk during SCS and DRG stimulation trials, including strict sterile technique during lead placement, exit-site dressing management with hydrocolloid and occlusive dressing, and adherence to the perioperative antibiotic regimen as outlined in the SIS Safety Practices for Spinal Cord and Dorsal Root Ganglion Stimulation and existing guidelines [2,21].

4) While current recommendations for surgical site infection prevention include administration of antibiotics prior to surgical incision and at most for 24 hours following surgery [2,3], there may be instances in which post-operative antibiotics beyond 24 hours are indicated during an SCS or DRG stimulation trial.

A) Data demonstrate that patients with comorbid diseases such as those with diabetes, malignancy, tobacco use disorder, remote infections, steroid exposure, Staphylococcus aureus carriers, and those who have undergone a prior spine surgery, have an increased risk of infection associated with surgical implantations [12], though this relationship has not been shown specifically in SCS trials.

B) Trials lasting more than five days have been associated with higher infection rates for the subsequent permanent implant [9]. For patients undergoing planned SCS or DRG trial for a duration greater than five days, or for those with certain comorbid diseases that may predispose to an increased risk of infection, administration of prophylactic antibiotics throughout the course of the trial should be considered. However, it must also be acknowledged that increased duration of antibiotics increases adverse drug events such as development of Clostridioides difficile and postoperative infection due to drug-resistant organisms [22].

5) Even with the appropriate pre-operative, intra-operative, and post-operative antibiotic prophylaxis in an otherwise healthy patient, development of an SEA remains a serious concern with SCS and DRG stimulation devices, and there should be a low threshold for repeating a spinal MRI if complications develop.
References


